

K963524

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 558-1500

NOV 14 1996

Contact: Kevin Kennan
Regulatory Affairs Specialist

Device Identification: Common Name:
Arthroscope

Trade Name: (optional)
Karl Storz Large Joint Arthroscopy Set

Indication: The KSEA Large Joint Arthroscopy Set is intended for arthroscopic procedures of the shoulder, knee and is also for the illumination and visualization of the hip joint to diagnose disease and for the removal of loose bodies in the hip joint.

Device Description: The Karl Storz Large Joint Arthroscopy Set are manually operated surgical devices. The KSEA Large Joint Arthroscopy Set is composed of Forward-Oblique 30° enlarged view Telescopes, Lateral 70° enlarged view Telescopes, Arthroscope Sheath with sharp and blunt obturators, Grasping and Biopsy Forceps, Trocar, and Inflow Cannula. The body contact portions of the KSEA Large Joint Arthroscopy Set are composed of surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

Substantial Equivalence: The Karl Storz Large Joint Arthroscopy Set is substantially equivalent to the predicate devices since the basic features and intended uses are similar. The minor differences between the Karl Storz Large Joint Arthroscopy Set and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: _____

Kevin Kennan

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Regulatory Affairs Specialist